THE DOCTOR, THE PATIENT, AND EU LAW: THE IMPACT OF FREE MOVEMENT LAW ON QUALITY STANDARDS IN THE HEALTHCARE SECTOR

Barend van Leeuwen*

University of Groningen

Abstract

This article analyses the impact of the free movement provisions on quality of healthcare in the EU. The application of the free movement provisions in the healthcare sector has restricted the freedom of Member States to set their own medical standards. International scientific evidence has to be taken into account. This impact reaches beyond the provision of cross-border healthcare. As a result, patients who are unable to travel abroad also benefit from higher medical standards. Individual challenges to national legislation under the free movement provisions are more successful in improving medical standards than adopting uniform European standards. Without a genuine internal market for healthcare services, European minimum standards do not contribute to improving the quality of healthcare in the EU.

Introduction

The judgments of the Court of Justice of the European Union ("the Court") in *Decker*[1] and *Kohl*[2] gave a very clear message to the Member States: although the EU does not have the competence to tell Member States how they should organise their healthcare systems,[3] this does not mean that the Court cannot review whether the way in which Member States have organised their healthcare systems is compatible with EU law. As a result, Member States have to comply with

* Assistant Professor of European Law, University of Groningen, The Netherlands. I am grateful to Carla Sieburgh and Jan Zglinski for their comments.

[1] *Decker* v *Caisse de maladie des employés privés* (C-120/95) [1998] E.C.R. I-1831.

[2] *Kohll* v *Union des caisses de maladie* (C-158/96) [1984] E.C.R. 3651.

[3] Article 168(7) TFEU now provides that "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of resources assigned to them".

the free movement provisions in the organisation of their healthcare systems. The judgments in *Decker* and *Kohl* were followed by a series of cases on the rights of patients to freely receive healthcare services in another Member State.[4] This series of cases resulted in the adoption of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare ("the Cross-Border Healthcare Directive").[5] The main aim of the Directive was to codify the case-law of the Court and to add a number of provisions on administrative cooperation between public authorities in the Member States. The impact of the Court's case-law and the Cross-Border Healthcare Directive on national healthcare systems has been analysed extensively in the literature.[6]

This article will focus on the impact of free movement law on the quality of healthcare that patients are entitled to receive under national healthcare systems. There are significant differences in the quality of healthcare that is provided in the Member States.[7] The financial crisis has put pressure on Member States to reduce costs and to cut budgets. This could lead to a reduction of the kind of medical treatments and the quality of healthcare.[8] The application of the free movement provisions to other social areas of law, such as employment law, has been criticised

[4] The most important cases were *Vanbraekel and others* v *Alliance nationale des mutualités chrétiennes* (C-368/98) [2001] E.C.R. I-5363; *Geraets-Smits* v *Stichting Ziekenfonds and Peerbooms* v *Stichting CZ Groep Zorgverzekeringen* (C-157/99) [2001] E.C.R. I-5473; *Müller-Fauré* v *Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen and van Riet* v *Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* (C-385/99) [2003] E.C.R. I-4509; *Inizan* v *Caisse primaire d'assurance maladie des Hauts-de-Seine* (C-56/01) [2003] E.C.R. I-12403 and *The Queen ex parte Watts* v *Bedford Primary Care Trust and Secretary of State for Health* (C-372/04) [2006] E.C.R. I-4325.

[5] Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.

[6] See, inter alia, J. Bacquero Cruz, "The Case Law of the European Court of Justice on the Mobility of Patients" in F. Benyon (ed.), *Services and the EU Citizen* (Oxford: Hart Publishing, 2013), p. 87; in the same volume: R. Cisotta, "Limits to the Rights to Health Care and the Extent of Member States' Discretion to Decide on the Parameters of Their Public Health Policies", p. 113; A. Dawes, " "Bonjour Herr Doctor": National Healthcare Systems, the Internal Market and Cross-Border Medical Care within the European Union" (2006) 33 Legal Issues of Economic Integration 167; V. Hatzopoulos, "Killing National Health and Insurance Systems but Healing Patients? The European Market for Health Care Services after the Judgments of the ECJ in Vanbraekel and Peerbooms" (2002) 39 C.M.L. Rev. 683; W. Palm and I. Glinos, "Ensuring Patient Mobility in the EU: Between Free Movement and Coordination" in E. Mossialos et al. (eds), *Health Systems Governance in the EU: The Role of EU Law and Policy* (Cambridge: CUP, 2010), p. 509.

[7] H. Legigo-Quigley et al., "Quality and safety" in M. Wismar et al., *Cross-border Health Care in the European Union* (Copenhagen: EOHSP, 2011), p. 121.

[8] M. Karanikolos et al., "Financial crisis, austerity and health in Europe" (2013) 381 Lancet 1323; M. Frischhut and R. Levaggi, "Patient mobility in the context of austerity and an enlarged EU: The European Court of Justice's ruling in the Petru case" (2015) 119 Health Policy 1293.

for leading to lower standards of protection and a race to the bottom,[9] and similar criticism has been made about their impact on the healthcare sector.[10] However, the application of the free movement provisions to the healthcare sector has the potential to improve quality of healthcare in the EU. This potential reaches beyond the provision of cross-border healthcare – i.e. to patients who travel to another Member State for medical treatment – and also has an impact on patients who remain in their home Member State.[11] The free movement provisions require Member States to assess the quality of healthcare that patients are entitled to receive in their home Member State and to compare this with the quality of healthcare provided in other Member States. International scientific evidence and international medical standards have to be taken into account. Article 4(1)(b) of the Cross-Border Healthcare Directive provides that medical treatment shall be provided in accordance with the standards laid down by the Member State of treatment. However, recent case law of the Court of Justice of the European Union ("the Court") shows that the comparative assessment required by the free movement provisions can force Member States to make available healthcare which would not have been made available to patients if the free movement provisions had not been applied. This impact is particularly visible in Member States that do not have many medical standards in place, or in Member States where the quality of healthcare is relatively low in comparison with other Member States.

The impact of free movement law on healthcare standards will be analysed by focussing on three "layers" of EU regulation. First of all, we will look at the impact of Article 56 TFEU. The main impact of Art. 56 TFEU has been to harmonise the procedural standards with which Member States have to comply in deciding whether a patient should be authorised to receive medical treatment in another Member State. However, through the inclusion of certain procedural conditions, the Court has already started to encourage a process of Europeanisation of the

[9] S. Deakin, "Regulatory Competition after *Laval*" (2008) 10 Cambridge Yearbook of European Legal Studies 581.
[10] C. Newdick, "Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity" (2006) 43 C.M.L. Rev. 1645; M. Ferrera, "Beyond National Social Rights?" in N. McEwen and L. Moreno (eds.), *The Territorial Politics of Welfare* (London: Routledge, 2005), p. 225.
[11] See also M. Flear, "Developing Euro-Biocitizens Through Migration for Healthcare Services" (2007) 14 Maastricht J. Eur. & Comp. L. 239.

medical standards that regulate quality of healthcare at the national level. Secondly, the Cross-Border Healthcare Directive has gone one step further and has positively harmonised the information requirements that a doctor has to comply with to guarantee that a patient is able to provide informed consent to treatment.[12] Although these standards have been harmonised in the context of cross-border healthcare, it is unlikely that Member States will make a distinction between treatment to national and non-national patients. Furthermore, the Cross-Border Healthcare Directive has introduced the concept of good quality healthcare.[13] While this concept has not expressly found its way into the case-law of the Court yet, it limits the freedom of Member States to determine the quality of healthcare they provide to their citizens. Finally, the article will analyse self-regulation at the European level by looking at European standardisation in the healthcare sector. In a number of healthcare sectors attempts have been made to agree on European standards through European standardisation. It is clear that it is much more difficult to agree on a set of European standards than to challenge national legislation under the free movement provisions. Moreover, the adoption of European standards in the healthcare sector could actually lead to lower medical standards throughout the EU. The differences in quality standards serve as a catalyst in encouraging Member States to adopt higher quality standards. Through their reliance on free movement law, patients from Member States with lower medical standards "bring home" higher quality standards and new medical treatments. Member States have to take these standards into account also at the national level. Such a strategy to improve quality standards in the healthcare sector would be more successful than aiming to adopt one uniform set of European healthcare standards.

The right to freely receive services in Article 56 TFEU

The general principles and the impact on procedural standards

[12] Article 4(2)(b) of the Cross-Border Healthcare Directive.
[13] Article 4(1) of the Cross-Border Healthcare Directive.

The key outcome of the Court's judgments in *Kohl* and *Decker* was that the right of patients to receive healthcare services in another Member State was included in the scope of application of Article 56 TFEU. The general rule developed by the Court was that Member States were obliged to reimburse the costs of medical treatment in another Member State at the same rate they would have paid if treatment had taken place in the home Member State. If the treatment in the other Member State was more expensive, the patient would only receive the amount of compensation he would have received in the home Member State.[14] Moreover, for medical treatment that required hospitalisation in the Member State of treatment, the home Member State was allowed to require a patient to obtain prior authorisation before going abroad for treatment. The subsequent cases before the Court focussed mainly on the procedural requirements that Member States had to comply with in deciding whether to grant prior authorisation for treatment in another Member State. Member States have to have transparent procedures in place, and decisions have to be taken within a reasonable period of time. They have to be open to judicial or quasi-judicial review.[15] It is no longer possible for Member States to refer to the acceptable length of national waiting lists as a reason to refuse authorisation. Each case has to be assessed individually and the individual circumstances of a patient should properly be taken into account.[16] This has effectively imposed an obligation on Member States to introduce flexibility in their waiting lists.[17] Finally, because Member States are obliged to reimburse the costs of treatment abroad up to the level of compensation a patient would have received in the home Member State, Member States have had to improve the transparency of the costs of medical treatment.[18] In Member States with a healthcare system based on benefits in kind, such as the United Kingdom,

[14] Conversely, if the treatment in the other Member States was cheaper than the treatment in the home Member State, the patient can still be compensated up to the level he would have received in the home Member State: *Vanbraekel* (C-368/98).
[15] *Geraets-Smits* (C-157/99) at [90].
[16] *Watts* (C-372/04) at [119-120].
[17] See J. Montgomery, "Impact of European Union Law on English Healthcare Law" in M. Dougan and E. Spaventa (eds), *Social Welfare and EU Law* (Oxford: Hart Publishing, 2005), p. 154.
[18] J. Montgomery, "Impact of European Union Law on English Healthcare Law" in M. Dougan and E. Spaventa (eds), *Social Welfare and EU Law* (Oxford: Hart Publishing, 2005), p. 154-155.

the costs of treatments have to be made accessible to patients – even if they would not normally see the price of these treatments because they do not have to pay for them.[19]

Overall, the Court's case-law has resulted in the creation of a set of European standards Member States have to comply with in the process of reimbursing or authorising medical treatment in another Member State. These procedural standards do not have an impact on the medical standards that are applicable to the medical treatment in another Member State. The possibility of free movement of patients could encourage Member States to exchange national standards – as we shall see later, this is something which is expressly confirmed by the Cross-Border Healthcare Directive –[20], but it does not require them to move from national standards to European standards.

Towards an impact on medical standards: Smits-Geraets and Peerbooms

Despite the fact that the main impact of the case-law under Article 56 TFEU has been on procedural standards, the procedural standards imposed by the Court have also had a spill-over effect on standards that directly regulate medical treatment. This is clear from the Court's judgment in *Smits-Geraets and Peerbooms*. Mrs Smits-Geraets was a Dutch national who had Parkinson's disease. She wanted to go to a specialised centre in Germany for multidisciplinary treatment that she claimed was not available in the Netherlands. Mr Peerbooms fell into a coma after a road accident. After a while he was transferred to a hospital in Innsbruck (Austria) to receive experimental neuro-stimulation treatment that was not available in the Netherlands. In both cases the Dutch health insurer refused to provide authorisation for treatment in another Member State. In Mr Peerbooms' case this meant that his treatment in Austria would not be reimbursed by the health insurer. For Mrs Smits-Geraets, this decision was taken primarily on the ground that adequate treatment was available in the Netherlands and that there was no medical

[19] E. Zanon, "Implications of the EU Directive on cross-border health care for the English NHS" (2011) 17 Eurohealth 34.
[20] Article 10 of the Cross-Border Healthcare Directive.

necessity for her to obtain treatment in another Member State. In the case of Mr Peerbooms, the refusal to provide reimbursement was based on scientific uncertainty about the effectiveness of neuro-stimulation. Furthermore, it was argued that adequate treatment was available in the Netherlands.

The Court used the case to provide further guidance on the criteria that Member States were entitled to use in procedures for requests for prior authorisation. The decision of the Dutch health insurers to refuse authorisation – or, in Mr Peerbooms' case, reimbursement – of treatment in another Member State constituted a restriction of the patients' right to freely receive healthcare services in another Member State.[21] This refusal could be justified by the aim to guarantee that patients had "sufficient and permanent access to a balanced range of high-quality hospital treatment in the State concerned".[22] However, the Court then specifically analysed the conditions applied by the health insurers. It focussed on two conditions: firstly, that the treatment for which prior authorisation was requested had to be "normal in the professional circles concerned"; secondly, that the medical treatment was "necessary" – in other words, that there was a medical necessity to be treated in another Member State. As to the necessity requirement, the Court held that Member States could refuse prior authorisation of treatment if they could show that the same or equally effective treatment could be obtained without undue delay in the home Member State.[23] This required a comparison between the potential treatment in the home Member State and the treatment abroad. As to the requirement that the treatment in the other Member State had to be "normal", the Court held that "to allow only treatment habitually carried out on national territory and scientific views prevailing in national medical circles to determine what is or is not normal will not offer those guarantees and will make it likely that Netherlands providers of treatment will always be preferred in practice".[24] Therefore, Dutch

[21] *Geraets-Smits* (C-157/99) at [69].
[22] *Geraets-Smits* (C-157/99) at [72-75].
[23] *Geraets-Smits* (C-157/99) at [103].
[24] *Geraets-Smits* (C-157/99) at [96].

health insurers were required to take into account international scientific evidence – the question was whether the requested treatment had been "sufficiently tried and tested by international medical science".[25]

The requirement that Member States consider international medical science in deciding whether treatment is normal means that Member States cannot rely exclusively on national standards. The Court has imposed an obligation on Member States to analyse international scientific evidence that is available in a particular field of medicine. Member States have to assess to what extent their national healthcare system is able to provide healthcare services in accordance with that international scientific evidence. From this perspective, it can no longer be maintained that Member States can assess requests for prior authorisation exclusively from the perspective of national standards of treatment. It is important to emphasise the link between international scientific evidence and medical standards. Most standards in the healthcare sector are evidence-based, which means that they are directly based on (international) scientific research.[26] Research in medicine has to an important extent been internationalised – many of the standards used in the EU are based on research which has been undertaken in the US.[27] While Member States retain discretion in deciding how international scientific evidence should be interpreted and how it should be "translated" to national medical practice,[28] the fact remains that they can no longer close their eyes to what is happening in international medical science and to standards that have been adopted on the basis of international medical science.

In *Smits-Geraets and Peerbooms* the Court made a direct link between free movement law and evidence-based medicine. Although Member States are only obliged to assess international

[25] *Geraets-Smits* (C-157/99) at [94].
[26] J. van Everdingen et al. (eds), *Evidence-based richtlijnontwikkeling: een leidraad voor de praktijk* (Houten: Bohn Stafleu, 2004). See also E. Freidson, *Profession of Medicine: A Study of the Sociology of Applied Knowledge* (Chicago: UCP, 1988).
[27] N. Cortez, "International Health Care Convergence: The Benefits and Burdens of Market-Driven Standardization" (2008) 26 Wisconsin International Law Journal 646.
[28] A. Den Exter, "Health Care Access in the Netherlands: a True Story" in C. Flood and A. Gross (eds), *The Right to Health at the Public/Private Divide* (Cambridge: CUP, 2014), p. 200. See also G. Davies, "Legislating for Patients' Rights" in J. van der Gronden et al. (ed.), *Health Care and EU Law* (The Hague: Asser, 2011), p. 204.

scientific evidence in the context of requests for authorisation to obtain treatment in another Member State, this obligation to go beyond national standards also has an impact on medical treatment without a cross-border element. The obligation to refer to international medical science arose in the context of deciding what is "normal treatment", which is a concept that is also relevant to medical treatment at the national level. This was already clear in *Smits-Geraets and Peerbooms*, because the Dutch health insurers were not allowed to discriminate between foreign healthcare providers and national healthcare providers with which they had not concluded contracts – which meant that patients could not go to these *national* providers without obtaining prior authorisation either.[29] Through the obligation to assess international scientific evidence, the interpretation of what constitutes "normal" treatment at the national level is changed. Patients who have not travelled to another Member State for treatment also benefit from this.

The Cross-Border Healthcare Directive 2011

Harmonisation of information duties

The main aim of the Cross-Border Healthcare Directive was to confirm and codify the case law of the Court and to clarify a number of concepts which had been developed in the case-law.[30] The Directive establishes a right for patients to receive treatment in another Member State and to be reimbursed for this treatment up to the level of costs patients would have received if they had stayed in their home Member State.[31] It also provides a clearer definition of hospitalisation, which is now restricted to treatment for which a patient has to spend a night in hospital.[32] Therefore, Member States are no longer entitled to impose a system of prior authorisation for out-patient treatment in a hospital in another Member State which is provided on the same day. Article 4(1)(b) provides that cross-border healthcare shall be provided in accordance with "standards and

[29] *Geraets-Smits* (C-157/99) at [93].
[30] For a detailed discussion, see S. De La Rosa, "The Directive on Cross-Border Healthcare or the Art of Codifying Complex Case Law" (2012) 49 C.M.L. Rev .15. See also W. Sauter, "Harmonisation in healthcare: the EU patients' rights Directive" (2011) TILEC Research Paper 6.
[31] Article 7 of the Cross-Border Healthcare Directive.
[32] Article 8(2)(a)(i) of the Cross-Border Healthcare Directive.

guidelines on quality and safety laid down by the Member State of treatment". As such, the Member State of treatment determines the quality of healthcare to which patients are entitled. However, while the Directive does not impose a certain level of healthcare on the Member States, it places an obligation on them to have standards in place. In order to be able to provide information about the applicable medical standards, which is required under Article 4(2)(a), Member States have to be able to provide information about the applicable medical standards in their territory. If Member States do not have such medical standards in place, they would not be able to fulfil their obligations under the Directive. As a result, the implementation of the Directive has resulted in a more proactive attitude by a number of Member States in adopting – or encouraging the adoption of – medical standards. This can be observed in some of the newer Member States and in some older Member States.[33] If there are no national standards, Member States may decide to rely on international or European standards.[34] As a result, the application of free movement law again stimulates a process of internationalisation or Europeanisation of medical standards. Moreover, in some Member States that already have plenty of medical standards, the Directive has encouraged the Member States to be more transparent about the applicable medical standards.[35]

One of the main novelties of the Cross-Border Healthcare Directive is that it also imposes a number of information duties on healthcare providers. In doing so, the Directive aims to give patients a number of consumer-like rights which are necessary to ensure that they are able to provide informed consent to treatment.[36] Article 4(2)(b) of the Directive imposes a number of obligations on healthcare providers. They have to provide information about the treatment

[33] S. Olsena, "Implementation of the Patients' Rights in Cross-Border Healthcare Directive in Latvia" (2014) 21 European Journal of Health Law 46, 51; M. Schwebag, "Implementation of the Cross-border Care Directive in EU Member States: Luxembourg" (2014) 21 European Journal of Health Law 56, 64.
[34] M. Schwebag, "Implementation of the Cross-border Care Directive in EU Member States: Luxembourg" (2014) 21 European Journal of Health Law 56, 62.
[35] L. Bongers and D. Townend, "The Implementation of the Directive on the Application of Patients' Rights in Cross-border Healthcare in the Netherlands" (2014) 21 European Journal of Health Law 65, 73.
[36] This was the approach argued for by G. Davies, "The Community's Internal Market-Based Competence to Regulate Healthcare: Scope, Strategies and Competences" (2007) 14 Maastricht J. Eur. & Comp. L. 215.

options, about the availability of healthcare, about the quality and safety of healthcare and about the prices and invoices for the treatment. By granting these information rights to patients the Directive enters directly "into the treatment room" and requires Member States to guarantee that doctors provide a certain amount of information to patients. This constitutes harmonisation of the information duties imposed on healthcare providers. In principle, it is limited to information provided to patients in the context of cross-border healthcare. The various information duties mentioned in Article 4(2)(b) only apply to healthcare that is provided to patients from another Member State. However, in fact, it is unlikely that Member States will create separate information duties for national patients and patients from other Member States.[37] The only element where a distinction could be made is with respect to the language in which the information is provided.

The final part of the Cross-Border Healthcare Directive which should be discussed is Chapter IV on cooperation in healthcare. This Chapter encourages Member States to exchange information. Article 10 on mutual assistance and cooperation provides that "Member States shall render such mutual assistance as is necessary for the implementation of this Directive, including cooperation on standards and guidelines on quality and safety and the exchange of information".[38] Such an exchange of information between Member States could lead to the realisation that it might be more convenient to adopt European standards in a particular field or sector. However, the Directive does not go beyond the mere exchange of national standards and guidelines – there is no direct encouragement of the adoption of European standards.

The concept of good quality healthcare: the impact of Elchinov and Petru

Similarly to the potential impact of the case-law under Article 56 TFEU through the interpretation of the concept of "normal treatment" in *Smits-Peerbooms*, the Cross-Border Healthcare Directive could have a more indirect impact on the freedom of Member States to

[37] D. Delnoij and W. Sauter, "Patient information under the EU's patients' rights Directive" (2011) 21 European Journal of Public Health 271.
[38] Article 10(1) of the Cross-Border Healthcare Directive

determine their own quality standards in the healthcare sector. Article 4(1) states that in providing cross-border healthcare Member States shall take into account the principle of "good quality care". The Directive also refers a number of times to the concept of "a balanced range of high-quality treatment in the Member State concerned".[39] The two concepts are not expressly defined in the Directive – it is not indicated what level of healthcare should be provided in order to comply with the principle of good quality healthcare. It could be argued that, because there is no express reference to national standards, the two concepts are autonomous EU law concepts that are not affected by the Member States' interpretation of good quality or high-quality care. However, because the whole Directive is expressly based on the idea that medical treatment shall be provided in accordance with national quality standards laid down by the Member State of treatment, it is difficult to argue that the concepts of good quality and high-quality care should be given an autonomous European interpretation. Nevertheless, it is clear that these references are strongly influenced by the aim to protect fundamental rights. Article 35 of the Charter of Fundamental Rights ("the Charter") protects the right of patients to have access to preventive healthcare. In combination with the concept of good quality care, it could have an impact on the interpretation of the Cross-Border Healthcare Directive.[40] This will be illustrated by an analysis of the Court's judgments in *Elchinov*[41] and *Petru*.[42]

Mr Elchinov was a Bulgarian national who was covered by the Bulgarian health insurance system. He had a tumour in his eye and the only treatment that was available in Bulgaria was the complete removal of the eyeball. More advanced treatment, that would not require the complete removal of the eyeball, was available in Germany. Therefore, Mr Elchinov applied for prior authorisation to be treated in a specialist clinic in Berlin. Because of the urgency of the situation he did not wait to hear the result of his application. The relevant Bulgarian legislation provided

[39] Article 1(1), Article 4(3), Article 7(7), Article 7(9) and Article 8(2)(a) of the Cross-Border Healthcare Directive.
[40] See also T. Hervey and J. McHale, *European Union Health Law* (Cambridge: CUP, 2015), p. 163-165.
[41] *Elchinov* v *Natsionalna zdravnoosiguritelna kasa* (C-173/09) [2010] E.C.R. I-8889.
[42] *Petru* v *Casa Judeteana de Asigurari de Sanatate Sibiu* (C-268/13) ECLI:EU:C:2014:2271.

that patients covered by the Bulgarian health insurance were entitled to "other operations on the eyeball" and to "high-technology radiotherapy for oncological and non-oncological conditions".[43] The Bulgarian authorities held that this did not include the highly specialised treatment that Mr Elchinov received in Berlin and refused to provide authorisation. This was because the treatment was not available in Bulgaria. As a result, Mr Elchinov, who had already received the treatment in Berlin, had to pay the costs of the treatment himself. He appealed against the refusal of the Bulgarian authorities to reimburse his treatment. Before the Bulgarian court, it was confirmed by an expert that the treatment Mr Elchinov had received in Germany was not available in Bulgaria.[44]

The Court had to decide if medical treatment that was not available in Bulgaria could still be held to be covered by the Bulgarian health insurance system. The Bulgarian legislation referred to "other operations on the eyeball", which was a relatively open category that had been interpreted restrictively by the Bulgarian authorities. The question was if this restrictive interpretation breached Mr Elchinov's right to freely receive services under Article 56 TFEU. The Court held that national authorities could not presume that "hospital treatment which cannot be given in the Member State on whose territory the insured person resides is not included in the benefits for which reimbursement is provided for by the legislation of that State or, conversely, that the hospital treatment included in those benefits can be given in that Member State".[45] As a result, the Bulgarian authorities could not simply presume that because the specialist treatment available in Germany could not be offered in Bulgaria, it was not covered by the Bulgarian health insurance system. As a result, the Court has effectively imposed a duty of consistent interpretation on national courts. However, it is a special kind of consistent interpretation, which is based on the vagueness of provisions of national law. If it is at all possible to bring a foreign treatment within the category of treatments that are reimbursed by the home Member State, the

[43] *Elchinov* (C-173/09) at [11].
[44] *Elchinov* (C-173/09) at [18].
[45] *Elchinov* (C-173/09) at [73].

national court should do so. This kind of duty of consistent interpretation is different from the traditional doctrine of consistent interpretation in the field of directives, where there are clear EU law rights that have to be accommodated in national law by relying on the potential openness or vagueness of national law. The duty of consistent interpretation developed in *Elchinov* works the other way around – it starts with the vagueness of national law, which subsequently creates an obligation to interpret it in the most "free-movement-friendly" way. This duty could also have an impact on the availability of the treatment at the national level – if a treatment is found to be covered by the home Member State, this also encourages healthcare providers to provide the treatment to patients who are not receiving cross-border healthcare.

In *Elchinov*, Bulgaria was in a way punished for using the relatively open category of "other operations on the eyeball" in the relevant Bulgarian legislation. The open character of the category enabled the Court to hold that in such cases the national authorities ruling on requests for prior authorisation should find that a specialist treatment was included in the treatments covered by the home Member State. This could result in Member States defining the categories of treatments that are covered by the home Member State in a much more restrictive way, with the result that they leave no doubt as to the treatments that are covered.[46] A duty of consistent interpretation would then not be possible, because it cannot be used in cases where the national legislation provides that a particular kind of medical treatment is not covered. Such a restrictive policy could potentially be in breach of the Cross-Border Healthcare Directive or Article 56 TFEU.[47] *Elchinov* could be used to argue that the concept of good quality healthcare prevents Member States from going below a certain level of quality and that certain medical treatments *have* to be covered by the home Member State's insurance system. This would also have an important impact on the medical standards that would be applicable to these treatments. Again,

[46] T. Sokol, "Rindal and Elchinov: A(n) (Impending) Revolution in EU law on Patient Mobility?" (2010) 6 Croatian Yearbook of European Law and Policy 167. See also A.P. van der Mei, (2011) 48 C.M.L. Rev. 1297, 1306.
[47] S. Greer and T. Sokol, "Rules for Rights: European Law, Health Care and Social Citizenship" (2014) 20 European Law Journal 66, 83.

Member States would have to provide healthcare of a higher quality at the national level. The freedom of Member States to determine what kind of quality of healthcare is offered to patients is restricted. This can be seen in *Petru*. Ms Petru was waiting for complicated open heart surgery in a Romanian hospital, when she discovered that the hospital did not have some basic medical equipment and facilities. Therefore, she decided to travel to Germany for treatment. She later claimed reimbursement from her Romanian health insurer. Reimbursement was denied on the basis that the treatment was available within a reasonable period of time in Romania. The Court had to decide whether authorisation could be refused when a hospital did not have sufficient resources to offer a particular kind of treatment. It concluded that authorisation cannot be refused "where it is because of a lack of medication and basic medical supplies and infrastructure that the hospital care concerned cannot be provided in good time in the insured person's Member State of residence".[48]

Petru clarifies that a lack of resources in hospitals in the patient's home Member State constitutes a valid reason to travel abroad for treatment in another Member State. However, the main focus of the judgment is not on the cross-border aspect, but on the obligation that is imposed on the home Member State. The Court imposed an obligation on the Romanian court to assess whether the treatment she required could be provided in another hospital in Romania. This is not dissimilar to the duty of consistent interpretation imposed on national courts in *Elchinov* – the national court is required to do all it can to guarantee that a patient can receive adequate medical treatment in the home Member State. The effect of this obligation is that the Romanian health insurer has to do its best to ensure that Ms Petru could receive adequate treatment in a Romanian hospital *without* having to travel to another country. If the required quality of care cannot be provided in the hospital where Ms Petru was being treated, it would be necessary to look for other hospitals in Romania where the required quality of care could be provided. Cross-border healthcare only becomes legitimate when all options in the home Member State have been

[48] *Petru* (C-268/13) at [36].

assessed and have been found inadequate. As such, the application of free movement law again has an impact on the quality of healthcare that is provided in the home Member State. In future cases similar to *Petru*, an assessment will have to be made to determine whether adequate treatment can be provided in Romania. The potential "threat" of free movement of patients forces Member States to provide healthcare of a higher quality in their territory. As a consequence, it is no longer necessary for patients to travel across borders for treatment and that medical treatment of a higher quality will be offered in their home Member State.

European standardisation in the healthcare sector

The role of European standardisation in the healthcare sector

It is clear that Article 56 TFEU and the Cross-Border Healthcare Directive have an indirect impact on the freedom of Member States to determine the applicable quality standards for medical treatment. They limit the discretion of Member States to decide on the applicable medical standards. However, with the exception of the information duties in Article 4(2) of the Cross-Border Healthcare Directive, there has not been any harmonisation of medical standards at the European level. In theory, such harmonisation could be realised by relying on the EU's competence under Article 114 TFEU to improve the functioning of the internal market.[49] Differences in medical standards could make it less attractive for patients to travel to another Member State for treatment. However, it would first have to be shown that there is in fact an internal market for healthcare services and that the adoption of European standards would improve this internal market.[50] Furthermore, it is unrealistic to assume that Member States would be willing to accept European standards in the healthcare sector, since healthcare is a field in which Member States are particularly protective of their national sovereignty. The fact that

[49] For a detailed discussion, see D. Wyatt, "Community Competence to Regulate Medical Services" in M. Dougan and E. Spaventa (eds), *Social Welfare and EU Law* (Oxford: Hart Publishing, 2005), p. 131.
[50] The number of patients travelling to another Member State for medical treatment remains low. See European Commission, 'Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare' COM(2015) 241 final.

harmonisation of medical standards is unlikely does not mean that there are no alternative ways to adopt European standards in the healthcare sector.[51] "Softer" alternatives such as self-regulation or co-regulation could be possible.[52] At the European level, this opens up the possibility of European standardisation of healthcare services.

European standardisation is a process of self-regulation at the European level. It has become prominent through product standardisation.[53] All Member States have their own national standardisation organisations, while the European standardisation organisation CEN is based in Brussels. If a European standard is made for a particular product, a so-called "technical committee" meets at CEN in Brussels to decide on the technical standards this product should comply with. The technical committee consists of representatives of national "mirror committees" that meet at the national standardisation organisations and that closely follow the European standardisation process. European standardisation is open to all stakeholders who are willing and able to participate – the result is that European standards can be made by businesses, consumer organisations, business associations and even by public authorities. All these parties meet in Brussels to agree on a set of European standards for a particular product. Once such a European standard has been adopted, it remains a self-regulatory instrument with no binding force in law *per se*.[54] However, Member States could decide to refer to such standards in legislation, in which case European standards would be applied in public law. Similarly, stakeholders in particular sector could apply standards in contracts – they could include a term in the contract that a particular product has to comply with a European standard – or in certification schemes. As such, European standards can also be applied in private law. Because it proved difficult to harmonise European product standards through the legislative process, the

[51] T. Hervey, "EU law and national health policies: problem or opportunity?" (2007) 2 Health Economics, Policy and Law 1.
[52] S. Greer and B. Vanhercke, "The hard politics of soft law: the case of health" in E. Mossialos et al. (eds), *Health Systems Governance in Europe*, (Cambridge: CUP, 2010), p. 186. See also S. Greer and T. Sokol, "Rules for Rights: European Law, Health Care and Social Citizenship" (2014) 20 European Law Journal 66, 86-87.
[53] For more background, see H. Schepel, *The Constitution of Private Governance* (Oxford: Hart Publishing, 2005).
[54] See H. Schepel and J. Falke, *Legal Aspects of Standardisation in the Member States of the EC and the EFTA, Volume 1: Comparative Report* (Luxembourg: Office for Official Publications of the European Communities, 2009).

EU decided to incorporate European standardisation in a new regulatory approach to goods – the "New Approach".[55] The basic idea behind the New Approach is relatively simple – the EU adopts general product safety directives which lay down the "essential requirements" with which products have to comply. The precise technical specifications are laid down in European standards developed through European standardisation. Once the reference of a European standard has been published in the OJEU, it is presumed that products that comply with the European standard also fulfil the essential requirements of the relevant directive. Although manufacturers are free to try and show by other means that they comply with the directive, in fact most of them choose to comply with the European standard. Therefore, European standardisation has obtained a prominent role in the EU's internal market for goods.

No such New Approach has been developed in the field of services. There are no European directives on the safety of services which are supplemented by European services standards. Although there is a reference to European standardisation of services as a tool to improve the quality of services in the Services Directive 2006,[56] this remains an isolated reference which is not embedded in a broader regulatory approach to services.[57] Nevertheless, in the last decade or so, a significant number of European services standards has been adopted through European standardisation.[58] European standardisation of services is a new regulatory tool in the services sector, which has been enthusiastically supported by CEN. European services standards define the level of quality service recipients are entitled to expect before, during and after the service process. It is not immediately clear what role these standards are supposed to play in the legal regulation of services. A second step is necessary to provide binding effect to European services

[55] Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards (85/C 136/01). See M. Egan, *Constructing a European Market: Standards, Regulation and Governance*, (Oxford: OUP, 2003).
[56] Article 26(5) of the Services Directive.
[57] B. van Leeuwen, "Free movement of services, European standardisation and private law" in H. Micklitz, Y. Svetiev and G. Comparato (eds.), *European Regulatory Private Law: The Paradigms Tested* (EUI Working Papers LAW 2014/04), p. 27. See also H. Micklitz, "The Services Directive: Consumer Contract Making via Standardisation" in A. Colombi Ciacchi et al. (eds.), Liability in the Third Millennium, (Baden-Baden: Nomos, 2009), p. 439.
[58] For an overview, see H. Micklitz, "Services Standards: Defining the Core Consumer Elements and their Minimum Requirements" Study Commissioned by ANEC, Brussels, April 2007.

standards in law. The healthcare sector is one of the sectors in which a number of European services standards has been made. Some European standardisation processes provoked very strong reactions by doctors, patients and public authorities. European standards in the healthcare sector interact directly with free movement law – in particular, with Article 56 TFEU. This will be shown through an analysis of a recent example of European standardisation in the healthcare sector.

A European standard for Cleft Lip Surgery Services

In January 2011 the European Cleft Organisation ("ECO"), a European patient organisation for babies born with cleft lips, submitted a proposal for a European standard for Cleft Lip Surgery to the Bulgarian standardisation organisation.[59] It had specifically chosen the Bulgarian standardisation organisation because it wanted to raise awareness in some of the new Member States. As a patient organisation, ECO's main aim was to ensure that there were minimum standards for cleft lip treatment in all EU Member States. Although it accepted that the standards are widely divergent across the EU, it argued that all EU citizens should be entitled to treatment in accordance with certain minimum standards. It was particularly concerned about the medical standards in Bulgaria and Romania. As such, there is a clear link to *Elchinov* and *Petru*. The Cross-Border Healthcare Directive is not of much use to patients with cleft lips, because babies born with cleft lips need a series of treatments during a number of years. Moreover, cross-border treatment is unrealistic because families of babies born with cleft lips in countries like Bulgaria or Romania do not usually have the financial resources to travel to another Member State for treatment. For those reasons, ECO wanted to develop a European standard that would empower patients and their families to demand a certain quality of care. Because a European standardisation process would potentially bring together various stakeholders from different Member States, ECO believed that European standardisation would be the best tool to adopt a

[59] BT N 8561 – (Draft Resolution BT C4/2011), Issue date: 2011-01-13.

European standard for Cleft Lip Surgery. A European standard would not override national legislation, which meant that the significant differences in national legislation should not be problematic.

After a proposal for a European standard has been submitted to one of the national standardisation organisations, all national standardisation organisations have to vote on whether they are in favour of the development of a European standard in that field. Two-thirds of the votes casted have to be in favour and there have to be at least five national standardisation organisations that are willing to actively contribute to the development of the standard.[60] In practice, this means that national standardisation organisations have to consult relevant stakeholders to see if they are in favour of a European standard and if they are willing to participate in a European standardisation process. For the European standard for Cleft Lip Surgery, national standardisation organisations consulted stakeholders in early 2011. They voted on the proposal in April 2011.[61] 15 national standardisation organisations voted in favour of the creation of a European standard, while 5 voted against. There were 11 abstentions. As a result, the proposal was rejected. The national standardisation organisations of Finland, France, Germany, the Netherlands and Spain voted against. The opposition in France and Spain was particularly strong. The French explained their negative vote with the following comments:

"Such a topic is considered as a very sensitive one linked to the patient safety. This is why in France the management of cleft lip and palate falls within the remit of the public authorities in charge of the health system, organised by dedicated regulations"[62]

[60] CEN Resolution BT C75/2009.
[61] Voting Results: "*Creation of a new CEN Project Committee for 'Healthcare services for cleft lip and/or palate'*", CEN BT/8561, Brussels, April 2011.
[62] Voting Results: "*Creation of a new CEN Project Committee for 'Healthcare services for cleft lip and/or palate'*", CEN BT/8561, Brussels, April 2011.

The main objection of the French was that medical standards should be set by public authorities at the national level rather than through self-regulation at the European level. The comments of the Dutch standardisation organisation were different:

"European standardization of healthcare services across Europe is unrealistic. Healthcare services for cleft lip and or palate in the Netherlands is aiming for optimal healthcare. Optimal healthcare might not be realistic (financially) for all individual countries. European standardization would most likely aim for an average level of healthcare. It is not in the interest of the Netherlands neither to develop nor to contribute to such a standard"[63]

After the negative vote ECO organised a number of meetings in France and Spain to try and increase the support for a European standardisation process. However, it became clear that there was not enough support. ECO then considered the possibility of making of Workshop Agreement through CEN, which would be an instrument with a lower status than a European standard. Because some national standardisation organisations were also against the adoption of a Workshop Agreement, ECO decided to develop a Technical Report through CEN. A Technical Report did not have the same status as a European standard or a Workshop Agreement, but it still provided an opportunity to lay down a number of European standards for cleft lip surgery. The Technical Report was adopted in March 2015.[64]

The case-study shows that European standardisation is one or two steps ahead of Article 56 TFEU and the Cross-Border Healthcare Directive. With European standardisation medical standards are defined directly at the European level. For the Cleft Lip Surgery standard, it was the inability of patients to exercise their free movement rights that encouraged ECO to take the initiative for one uniform European standard. Because of the limitations of the exercise of free movement rights, ECO wanted to raise the quality of healthcare at the national level in Bulgaria and Romania. It wanted to achieve this by adopting one uniform European standard that would

[63] Voting Results: "*Creation of a new CEN Project Committee for 'Healthcare services for cleft lip and/or palate'*", CEN BT/8561, Brussels, April 2011.
[64] CEN/TR 16824:2015, Technical Report on care services for babies born with cleft lip and/or palate.

be applicable to all Member States. However, a significant number of the Member States were not willing to abandon their national standards in favour of a European standard. Two main objections can be observed. First, the regulatory competence of the Member States to determine the applicable medical standards was challenged much more directly by European standardisation than by the application of Article 56 TFEU and the Cross-Border Healthcare Directive. Under the free movement provisions, individual patients challenge the level of quality of healthcare that is provided in their home Member State by trying to benefit from treatment of a higher quality in another Member State. This process forces Member States to reconsider the quality of healthcare that is provided in their territory. The impact at the national level is indirect. With European standardisation, Member States have to accept that standards are set directly at the European level. Moreover, they are not set by the Member States themselves, but by private parties such as patient organisations.[65] Quality of healthcare would be determined at the European level outside the direct control of the Member States. Although these European standards would not be binding in law, it is not surprising that Member States consider European standardisation as a threat to their regulatory competence.

Second, European standardisation does not only have an impact on *who* determines the quality of healthcare patients are entitled to receive, but also on *what* level of quality patients are entitled to receive. European standardisation introduces one uniform standard. It aims to remove differences in quality of healthcare between the various Member States. This is an important difference with the impact of Article 56 TFEU and the Cross-Border Healthcare Directive. The case law under Article 56 TFEU was primarily about patients who wanted to benefit from higher medical standards in another Member State. The basis of all cases was the existence of differences between the level of healthcare provided in the Member States. Changes in the quality of healthcare provided in the home Member State were required precisely because there were

[65] See M. Flear, "Developing Euro-Biocitizens Through Migration for Healthcare Services" (2007) 14 Maastricht J. Eur. & Comp. L. 239

(significant) differences. By imposing an obligation on Member States to assess international scientific evidence and to interpret national legislation consistently with this scientific evidence, Member States were put under pressure to increase medical standards at the national level. As a result, Member States were not required to lower medical standards.

However, the picture is different for European standardisation. This leads to a development from negative integration to positive integration. Differences between medical standards in the various Member States are removed by adopting one uniform European standard. One of the basic principles of European standardisation outside the New Approach is that it only provides minimum standards. Member States remain free to use or to adopt standards that go beyond the minimum standards provided in European standards. This raises the question in what circumstances Member States would actually benefit from having European minimum standards in place. After all, if Member States already have higher national standards, why would it be necessary for them to agree on European minimum standards? It is important to look at the reasons for adopting European minimum standards. Because of the inherent characteristics of the treatment of patients with cleft lips, there is no internal market for cleft lip surgery. ECO wanted a European standard to remedy the limitations of the internal market. It wanted to increase the level of care for patients who were unable to move to another Member State for treatment. However, it is clear that, in the absence of an internal market, Member States with higher standards have no interest in adopting European minimum standards. This is clear from the Dutch explanation for their negative vote on the proposal.[66] A European minimum standard would only result in pressure to lower current higher national standards. It would not be in the interest of these Member States to contribute to the adoption of European standards. European standardisation is rejected as a development aid tool to support some of the new Member States. These Member States regard European standardisation as initiating some sort of race to the

[66] Voting Results: "*Creation of a new CEN Project Committee for 'Healthcare services for cleft lip and/or palate'*", CEN BT/8561, Brussels, April 2011.

bottom, because they would have to agree on standards that are lower than their current medical standards. They are effectively saying that patients in countries with lower medical standards benefit more from the differences in standards – from certain Member States "setting the example" for other Member States – than from the adoption of one uniform European standard.

The interaction between free movement law and quality of healthcare

Harmonisation and standardisation in the healthcare sector: between positive and negative integration

The analysis above has shown that the application of the free movement provisions has had an impact on the quality of healthcare that patients are entitled to receive under national healthcare systems. This impact is not limited to patients who have exercised their free movement rights, but also extends to the provision of healthcare at the national level. However, the impact has been indirect. The Court has been cautious not to interfere directly with the regulatory competence of the Member States to determine their medical standards. However, it has restricted the margin of discretion of Member States and it has forced them to review medical standards in light of international scientific evidence. In combination with the reference to the concept of "good quality care" in the Cross-Border Healthcare Directive, this means that clear boundaries have been set at the European level to the level of quality of healthcare that is provided to patients. In addition, the Court has imposed a duty of consistent interpretation, which means that national courts have to interpret national legislation in such a way that the highest quality of healthcare which can be provided within the limits of the national legislation is actually offered to patients. Overall, the result is that the application of free movement law has had a positive impact on the quality of healthcare patients are entitled to receive under national healthcare systems.

The special characteristics of the healthcare sector have resulted in a rather different impact of the free movement provisions in comparison with other services sectors. Although the Court has

consistently held that Article 56 TFEU is applicable to healthcare services, the reality is that there is no real internal market for regular healthcare services.[67] Patients rarely travel to another Member State for medical treatment.[68] The cases that reached the Court primarily concerned wealthy citizens who had the financial means to profit from higher medical standards in other Member States, and who were subsequently able to reclaim the costs of medical treatment in their home Member States. Therefore, the main impact in the healthcare sector is more the result of the *potential* of free movement of patients than the *actual* cross-border movement of patients. Furthermore, it is not realistic to create one European level of quality of healthcare. Such a uniform level would not actually raise the overall quality of healthcare in the EU. Member States with higher medical standards are afraid that the removal of differences in quality would result in a lower overall level of quality of healthcare. The dynamics of the free movement provisions in the healthcare sector are special. Patients benefit most from trying to profit from differences in the quality of healthcare between Member States. As such, for free movement law to have a positive impact on the quality of healthcare, it is crucial that differences in national quality standards remain. The most effective strategy to improve medical standards at the national level is to use the free movement provisions as a tool to confront Member States with higher quality standards and to use free movement law to explore the potential of national legislation to apply these higher medical standards at the national level. This is the combined effect of *Smits-Geraets*, *Elchinov* and *Petru*.

As a result, it would not actually be beneficial to attempt to harmonise or standardise quality of healthcare at the European level. The internal market for healthcare services is best served by maintaining differences between Member States. These differences encourage a race to the top

[67] See European Commission, "Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare" COM(2015) 241 final. This is different from, for example, cosmetic surgery, where patients frequently travel across borders for (cheaper) treatment in another Member State. For the consequences, see B. van Leeuwen, "PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies"(2014) 4 European Journal of Risk Regulation 338.
[68] For the American perspective, where cross-border healthcare is much more common, see N. Cortez, "Patients Without Borders: The Emerging Global Market for Patients and the Evolution of Modern Health Care" (2008) 83 Indiana Law Journal 71.

rather than a race to the bottom. European minimum standards would reduce differences and, as a consequence, would reduce the incentives for Member States to improve quality of healthcare. From a free movement perspective, this might be an unusual conclusion. For other sectors, the functioning of the internal market can best be guaranteed by having minimum standards of protection in place. Such minimum standards would not work in the healthcare sector. For the free movement provisions to be used as an effective tool to improve quality of healthcare, it is essential that differences in quality remain. The conclusion is that harmonisation and standardisation of medical standards at the European level should be resisted. The usual combination of positive and negative integration does not work in the healthcare sector. While positive integration by way of harmonisation would normally be the logical next step after negative integration through the removal of obstacles to free movement of services,[69] the focus to improve quality of healthcare in the EU should solely be on negative integration.

Individual rights as a catalyst for improving quality of healthcare

Even without European harmonisation or standardisation in the healthcare sector, it is clear that Member States are no longer in exclusive control of the setting of medical standards. Private parties, such as associations of doctors or patient organisations, use the European perspective of the free movement provisions to try and force Member States to raise medical standards. The Cleft Lip Surgery example illustrates that patient organisations have tried to do this by campaigning for one European standard. This attempt failed because of resistance in some Member States with higher national standards. As a result, it would be more effective if patient organisations focussed on facilitating free movement of patients from Member States with a lower quality of healthcare to Member States with higher medical standards. For example, patient organisations could provide funding to patients to get medical treatment in another Member State. After the treatment, they could help them to obtain reimbursement from their home

[69] J. Snell and M. Andenas, "Exploring the outer limits: restrictions on the free movement" in M. Andenas and W. Roth (eds), *Services and Free Movement in EU Law* (Oxford: OUP, 2002), p. 83.

Member State. Such a strategy would be more successful in raising the level of healthcare at the national level than to invest in the adoption of uniform European standards. Collective attempts to raise medical standards in certain Member States have the best chance of success if they collectively facilitate individual challenges to national medical standards. This might seem counterintuitive or even paradoxical, but it is not a new strategy at the European level.[70]

The result is that through the exercise of their free movement rights patients "bring home" higher medical standards. The free movement provisions force Member States to take these standards into account. It is true that the motives of patients might have been egocentric. Mr Elchinov and Ms Petru were not aiming to raise the quality of care for all patients in Bulgaria and Romania – they just wanted to obtain the best possible treatment for themselves. However, they still acted as "explorers" for other patients who were unable to rely on their free movement rights. It was only through the exercise of their free movement rights that they were able to force their national healthcare systems to take higher medical standards into account. It could be argued that most of these cases were about the *availability* of medical treatments, and not about the *quality*. However, there is close relationship between the availability of medical treatments, the quality of healthcare and medical standards. The treatments patients were seeking in these cases were not available in the home Member States, because they were based on medical standards that had not yet made their way into the national healthcare systems. The effect of the application of Article 56 TFEU was to encourage Member States to make these treatments available in the home Member State, in accordance with medical standards. Because most medical standards are based on scientific evidence, the availability of treatments of a higher quality necessarily means that higher medical standards will be applicable.

[70] G. Davies, "The Community's Internal Market-Based Competence to Regulate Healthcare: Scope, Strategies and Competences" (2007) 14 Maastricht J. Eur. & Comp. L. 215 and M. Flear, "Developing Euro-Biocitizens Through Migration for Healthcare Services" (2007) 14 Maastricht J. Eur. & Comp. L. 239.

Finally, it remains problematic that Member States could potentially restrict the kind of medical treatments to which patients are entitled under the national healthcare system by creating more exhaustive and precise lists of medical treatments in national legislation. This remains the fear of patients in Member States where financial difficulties impose a big strain on healthcare budgets. However, it should be emphasised that such a rationing exercise would in itself be an expensive and time-consuming exercise for Member States. Cross-border movement of patients is not sufficiently common for it to be attractive for Member States to embark on such an exercise. Therefore, most Member States will continue to use relatively open-ended categories, which leave room for the incorporation of higher treatments and medical standards. If Member States really restricted healthcare to such an extent that certain essential medical treatments were no longer available, this would be the right occasion for the Court to give teeth to the concept of "good quality healthcare" in the Cross-Border Healthcare Directive. In combination with Article 35 of the Charter, this concept provides a powerful tool for the Court to argue that Member States cannot go below a certain minimum level of healthcare.

Conclusion

From the early judgments in *Kohl* and *Decker*, the impact of the free movement provisions on the healthcare sector has been analysed extensively. Most of this analysis has adopted a systemic perspective and has focussed on the effect of the application of free movement law on national healthcare systems. The article has shifted the perspective to the patient and to the quality of healthcare that patients are entitled to receive under national healthcare systems. The impact of free movement law on the standards that are applicable to medical treatment has been investigated through an analysis of the impact of Article 56 TFEU, the Cross-Border Healthcare Directive and European standardisation in the healthcare sector. The competence of the Member States to independently and autonomously determine the applicable standards for medical treatment has been restricted by the application of the free movement provisions. They have

forced Member States to engage in a comparative assessment of medical standards in the EU. As a result, they are obliged to open their eyes to what is going on in other Member States in terms of scientific evidence and medical standards. Although this obligation formally exists only in the context of cross-border healthcare, it also has an impact on the quality of healthcare that is provided to patients who are unable to travel to another Member State for medical treatment.

Overall, the free movement provisions have increased the quality of medical treatments that are available to patients at the national level. There has not been a race to the bottom and free movement law has helped patients. This does not come as a surprise, because in all cases that were discussed a central role was played by the patient. The pro-active attitude of patients has forced national healthcare systems to improve their quality of healthcare. The potential of cross-border healthcare has resulted in changes at the national level – not only to the benefit of travelling patients, but also to the benefit of less privileged patients who do not have the financial means to take the risk to travel to another Member State for medical treatment. As a result, patients have played and will continue to play a crucial role as campaigners for higher medical standards throughout the EU. The initiative for a European standard for Cleft Lip Surgery has shown that it is better to improve medical standards by challenging and exploring the full potential of national legislation than to aim for the introduction of uniform European standards. Such European standards would result in an average level of care and would remove incentives to improve quality of healthcare. Relying almost exclusively on negative integration means that differences in quality will remain, and that patients are encouraged to explore these differences. This process will be gradual, slow and dependent on private initiatives. Nevertheless, it has proved to be an effective strategy to improve medical standards throughout the EU.